IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application of: Leon M. Clements, et al.	)	Confirmation No.: 2679
Filed: March 23, 2004	)	Examiner: Phongsvirajati, Poonsin
Application No. 10/806,878	)	Group Art Unit: 4176
For: PHARMACEUTICAL INVENTORY AND DISPENSATION COMPUTER SYSTEM AND METHODS	)	Attorney Docket No. 0771CG.035249

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Toby Clark, R.Ph, B.S, M. Sc, FASHP, state the following:

1. I have a Bachelor of Science in Pharmacy degree, 1967 a Master of Science degree 1970, and an American Society of Hospital Pharmacists accredited hospital pharmacy residency program 1968, and have more than 38 years of hospital pharmacy experience, and extensive experience in hospital pharmacy management.

1a. I am currently a hospital pharmacy and medication systems consultant having extensive experience in the areas of pharmacy operations, computerized provider order entry (CPOE), and pharmacy/medication systems informatics. I am a former Director of Hospital Pharmacy Services at the University of Illinois at Chicago Medical Center, where I led the pharmacy in its conversion of a twenty-year-old CPOE system to a new vendor in 1999. I am also formerly a Professor of Pharmacy, College of Pharmacy, University of Illinois at Chicago and currently a Clinical Associate Professor at the South Carolina College of Pharmacy and consultant to the director of pharmacy at the Medical University of South Carolina in Charleston.

I have previously served as faculty at the University of Houston College of Pharmacy and Director of Pharmacy and pharmacy faculty at Kansas City General Hospital/University of Missouri at Kansas City. I have served several health care organizations in a variety of capacities, including Administrator and Chief Executive Officer, of the University of Illinois Eye and Ear Hospital, Director, of Hospital Pharmacy Studies at the University of Houston. I previously served as Director of Pharmacy and assistant hospital administrator in Texas City, Texas; Operations Executive at Searle Unit-Dose Systems, Inc., Skokie, Illinois; and Regional Pharmacy Manager for Hospital Affiliates International, Inc., Austin, Texas.

1b. I am the founder of Toby Clark, Inc., an independent medication system consulting organization, which has been providing services since 1979. In this capacity, I have assisted more than 425 health care providers, including the University of Toledo Medical Center, University of Virginia Medical Center, The University of Florida Health Sciences Center and College of Pharmacy, Hospital Corporation of America, American Medical International, Inc., the Methodist Hospital Healthcare System, Inc. (Houston), the University of Iowa Hospitals and Clinics, Georgetown University Medical Center, and The Johns Hopkins Medical Center, Inc., and have assisted various facilities ranging in size from 25 beds to over 1000 beds. I have also served as a hospital pharmacy management consultant to the American Society of HealthSystem Pharmacists. Other consulting engagements I have engaged in include operations improvements in the areas of improving pharmacy safety, quality and productivity, drug cost reduction practices, clinical service design, and medical staff and nursing customer service.

1c. I am a registered pharmacist and have been a member of the American Association Healthcare Consultants. I currently serve as Treasurer, of the Hospital Pharmacy Section, International Pharmaceutical Federation (FIP). I am also a member of the American Society of Hospital Pharmacists, Phi Delta Chi, and am a founding member of both Oncology Section of the Board of Pharmaceutical Specialties and the Novation Pharmacy Executive Committee. I am a past chair of the pharmacy executive committee and Council of the University Health-System Consortium.

1d. I am the founder of a computer system listserve dedicated to medication system computerization sponsored by the American Society of Health-System Pharmacists (ASHP)

which deals with issues related to POE and CPOE, and am a co-author of the publication titled "ASHP Landmines and Pitfalls of CPOE" as well as other publications in the area of pharmacy informatics. Various works of mine have appeared in several publications to include the American Journal of Hospital Pharmacy, Hospitals, Journal of the American Hospital Association, and Topics in Hospital Pharmacy Management. In addition, I have made presentations on a variety of topics relating to the operations of pharmacy services, collaboration with nurses and physicians, medication safety, CPOE and automated medication systems.

2. I am familiar with and understand the subject matter of the above-identified patent application ("Clements Patent Application"). I have studied the application and the amendments to the application, and have also reviewed the recent "Office Action" dated April 3, 2009, by the United States Patent and Trademark Office, identified as "Paper No. 20090328," and the references cited therein.

3. Particularly, I have read and studied, U.S. Patent Publication No. 2004/0088187 to Chudy et al. (hereinafter "Chudy") in view of a Department of Health report entitled "A Pharmacy Service for Prisoners" (hereinafter "DOH"), and further in view of U.S. Patent No. 7,278,028 to Hingoranee (hereinafter "Hingoranee"), along with the comments and evaluation performed by the Examiner of the Clements Patent Application in the Office Action. From the review, it is my reasoned opinion that the claimed embodiments of the Clements invention, Claims 1-36, are not rendered obvious to one of ordinary skill in the art at the time the Clements Patent Application was filed by the individual or any combined reference teachings. It is also my opinion that one of ordinary skill in the art would recognize the structural differences and advantages of the claimed embodiments of the Clements invention over that of the cited documents. Such differences are also shown by the failure of others to recognize the source of the problem and to provide an effective solution.

4. I, however, also offer the following more detailed comments on these issues as well:

4a. Claimed Invention: Various claimed embodiments of the Clements invention feature, for example, computerized systems, program storage media/program product, and methods which can make comprehensive electronic medical records visible to the pharmacist to allow the pharmacist to make decisions regarding the suitability of physician prescribed

medications, beyond mere drug interactions, which can include provisions for a multistage electronic consumption documentation process which correspondingly includes documenting actual dispensation, receipt, and verified consumption of a prescribed medication, and which can include provisions for updating the electronic medical records and/or generating reports based upon whether the medication was consumed, to enhance/optimize a pharmacy management system for inmates. It is my opinion that such features are unique and operationally quite different than other pharmaceutical inventory and dispensing systems I have seen before. Further, it is my opinion that the electronic consumption documentation process is a significant development over the material described in the cited references which, even if hypothetically taken together, merely describes a pharmacy system to process pharmaceuticals for inmates which includes a verification process whereby it is verified that the proper medicine is packaged in the designated packaging container, and which uses biometrics to verify patient identity prior to handing the pharmaceutical to the patient. The Clements electronic consumption documentation process not only beneficially provides data to update an inmate's electronic medical record and/or computerized inmate record, but can produce data which can provide sufficient evidence needed to substantially reduce the number of grievances that could be even remotely justifiably filed against the correctional facility claiming that the correctional facility did not provide adequate medical care. Based on my review of the cited references, the Clements Patent Application, and the Office Action from the USPTO, it is my opinion that such features were nonexistent prior to the introduction of the Clements Patent Application.

4b. Structural Differences Over the Cited Documents.

4b1. The Clements Patent Application sets forth a recognition of the source of various problems which exist with pharmaceutical management and delivery in correctional facilities, such as, for example, the lack of access of pharmacists in a central pharmacy to correctional facility inmate records and correctional facility medication administration records and medical records; the lack of compatibility between databases; the lack of access to evidence of inmate consumption of prescribed medication; and the lack of effective inventory tracking (e.g., from the time the medication enters the pharmacy until the time and inmate takes the medication). Various claimed embodiments Clements Invention appear to me to solve such problems, for example, by making comprehensive electronic medical records visible to the

pharmacist, by making both comprehensive electronic medical records and correctional facility records visible to the pharmacist, by providing a multistage electronic consumption documentation process which includes documenting actual dispensing, receipt, and verified consumption of a prescribed medication, and by including provisions for updating the electronic medical records and/or generating reports based upon whether the medication was consumed emanating from the pill window technician level.

4b2. Note, based upon my review of the Clements Patent Application, and the context of the description to include integral use of pill windows, etc., it is my opinion that it would be clear that one skilled in the art would understand the various embodiments of the Clements Invention to be directed to outpatient medication delivery in correctional facilities and not delivery in a hospital environment or other closed medical system, which fall under a different set of rules and regulations. Accordingly, my comments on conventional systems for comparative purposes should be considered as being directed to open, outpatient type systems unless indicated otherwise.

4b3. Chudy describes a system and methods for managing a pharmacy workflow associated with fulfillment of prescription orders for medications and health-related products in a pharmacy environment. The system is described as sequencing prescriptions to minimize costs associated with filling of prescription orders, to minimize human involvement in the prescription order fulfillment process, to reduce the amount of time required to fulfill a prescription order, to reduce the spatial (walking) distance required to be traveled by pharmacy technicians to fulfill prescription orders, and to reduce the potential for errors in the fulfillment process. Notably, it is my reasoned opinion that Chudy does not teach that for which it has been cited--including a system or method which includes verifying suitability of a medication based on a review of an electronic medical record which can include a combined automated and/or manual process directed to a relatively comprehensive electronic medical record, or forming a record in a computer indicating a verification of whether a patient actually took the prescribed medication, following a verification of receipt by the inmate of the medication.

4b4. The DOH report by England's Department of Health describes findings and recommendations supporting a desire/goal to integrate prison pharmacy services into

England's national health services. Notably, it is my reasoned opinion that the DOH article does not teach the actual structure of functional systems, software, or process steps needed to try to build a pharmacy system. In fact, it appears to me that most, if not all of the recommendations provided in the report identify a shortfall in prison pharmacy services, without detailing the "hardware" or software needed to fix the shortfall.

4b5. Hingoranee describes systems and methods for crosshatching biometrics with other identifying data. Hingoranee further describes that it is applicable for use in controlled environment facilities, such as a prison or jail. In a section describing various prison uses, Hingoranee makes note that inmates may be provided medical services, such as the dispensing of prescription medications, and that proper authentication of the inmate's identity would be desirable in such instance. Notably, it is my reasoned opinion that Hingoranee does not teach that for which it has been cited--the formation of a record indicating the dispensing of a medication, the formation of a record indicating receipt of the medication, or the formation of a record indicating whether or not a patient actually consumed the medicine

4b6. I therefore conclude that the combined teachings of Chudy, DOH, and Hingoranee, if one were motivated or capable of combining such teachings, would not render obvious the claimed embodiments of the Clements Invention. I, however, offer additional discussion below:

4c. No Recognition of the Source of the Problem or Motivation to Combine Reference Teachings: Based upon my review of the cited references and my knowledge of industry practices, I conclude that nothing in either of the cited references recognizes the problems or solution identified by the Clements Patent Application as set forth in the claims. For example, Chudy sought to reduce the human involvement in the prescription order fulfillment process. The independent claims of the Clements Patent Application, however, specifically focus on added human involvement either directly via multistage documentation of consumption, or indirectly through providing additional access to additional records not previously available to the pharmacist to allow a more thorough suitability review including previously unavailable information. As such, it is my opinion that Chudy effectively teaches away from its utilization by one of ordinary skill in the art in order to try to piece together information to build the

claimed embodiments of the Clements Invention. Accordingly, is my opinion that there would have been no motivation to combine reference teachings to try to build the claimed embodiments of the Clements Invention at the time of the filing of the Clements Patent Application.

4d. The References Do Not Teach All Claim Elements.

4d1. Based upon my review of the cited references and my knowledge of industry practices, I conclude that neither Chudy, DOH, or Hingoranee, alone nor in combination, teach making comprehensive electronic medical records visible to the pharmacist to allow the pharmacist to make decisions regarding the suitability of physician prescribed medications, or provisions for a multistage electronic consumption documentation process which includes documenting actual dispensation, receipt, and verified consumption of a prescribed medication, in general, much less in the particular manner as featured in the claims, as presented in the claims of the Clements Patent Application.

4d2. Although the Office Action purports to state that one or more combinations of Chudy, DOH, or Hingoranee teach each and every element of each and every claim in the Clemens Patent Application, I wish to specifically address select statements made in the Office Action, which I must respectfully identify as being misconceptions, which I believe has inadvertently led to such conclusion. I note that on page 7, last paragraph, of the Office Action, it is stated (in paraphrase) that the combination of Chudy and the DOH reference does not indicate the unique consumption/compliance documentation procedures of: forming a record of dispensing a unit packet of the inmate's prescribed medication to the inmate, forming a receipt verification record indicating verification that the inmate received the unit packet, and forming an administration verification record indicating a verification indicating an actual physical verification that the patient consumed/did not consume the medication; but then premises that Hingoranee, citing its abstract and col. 8, lines 31-58, provides such teaching. I have reviewed the passages and wish to point out that the passages, instead, describe an authentication/identification process which includes iterative and successive cross-hatching of biometric components with other identifying data to ensure proper authentication/identification of a person such as the proper authentication of an inmate when dispensing prescription medications. I also wish to point out that performing a proper authentication or identification of

a prisoner at a pill window prior to dispensing medication is not a teaching or enabling disclosure to one of ordinary skill in the art of the unique multiple-record formation consumption documentation process detailed in the Clements Patent Application--particularly the formation of receipt verification and administration verification records in computer memory, the performance of an actual physical (human) verification that the inmate consumed the inmate's prescribed medication, or updating the inmate's electronic medical record by a computerized records computer responsive to receiving the administration verification record from a correctional facility unit computer.

4d3. I note that on page 6, in the first paragraph of para. 14 of the Office Action, in discussing records available to be reviewed by a pharmacist for a claim element directed to performing a verification that a prescribed medication is suitable for a patient, it is stated that "the patient's medical history [contained within an electronic medical record] is inherent since the pharmacist must determine what prescription has been approved for fulfillment which requires a patient's medical history..." I must point out that only a "prescription order" [which does not include a patient's medical history] is necessary to determine what prescription has been approved for fulfillment according to the teachings of Chudy, and thus, providing the pharmacist access to a patient's medical history would not be inherent, as premised in the Office Action. Accordingly, I must conclude that Chudy does not inherently teach making electronic medical records available to the pharmacist or the pharmacist performing a review on such records, much less reviewing an electronic medical record or authorizing release of a prescribed medication in response to verification that the medication is suitable based on the review of the electronic medical record.

4d4. Note, for the sake of thoroughness, I must further point out that even if Chudy had access to medication administration records, in either electronic form or otherwise, such records are not the equivalent of electronic medical records, which generally include laboratory work results (both current and historic), medical checkup data (including physician and/or nurse notes, vital signs, etc.), or medications prescribed but filled at other pharmacies, etc. I must also further note that based on my review of the references, neither of the references teach providing the pharmacist access to the inmate's correctional facility record, which can include information such as whether or not the inmate is transferring or due to be discharged, inmate

propensities, etc. It is my opinion that providing the pharmacist access to electronic medical records and providing access to the inmate's correctional facility records, whether provided individually or simultaneously, is new and not an obvious variant of conventional pharmacy procedures or systems.

4d5. I further note that on page 8, para. 15 of the Office Action, it is premised that "it is well known in the art to review an electronic medical record for duplicate therapies." I must point out that it is known to review dosing and dispensation records (e.g., medication administration records) for duplicate therapies, but not to examine or review actual inmate medical records, whether in paper or electronic form, which if accomplished, would give a more complete view of the patient profile than would have been conventionally available--allowing the pharmacist to identify duplications that would not otherwise be identified.

4d6. I also note that on page 8, para. 16 of the Office Action, it is premised that it "is well known in the art to review laboratory results contained within [an] electronic medical record." Again, I must point out that access to laboratory results, both current and historic, was not in the purview of data available to the open system pharmacist, or even that which would be expected to be reviewed by a closed system pharmacist.

4d7. Finally, I wish to note a few additional points not discussed in the Office Action. Specifically, I wish to point out that neither of the cited references teach remotely (locally) caching in the pharmacy database each electronic medical record for each inmate contained within each prescribed medication shipment of a plurality of prescribed medication shipments scheduled to be shipped within a predefined time period prior to a pharmacist reviewing the respective inmate's electronic medical record and prescription order and/or caching data related to each label to be printed for each shipment scheduled to be shipped within the predefined time period prior to printing the label to thereby prevent a potential disruption of medication delivery resulting from a breakdown in network communications between a pharmacy server/computer and a computerized records computer storing electronic medical records.

4d8. I also wish to point out that neither of the cited references teach receiving a data entry from a correctional facility pill window technician for a correctional facility unit

indicating an allergic reaction to the inmate's prescribed medication, or updating the inmate's electronic medical record over a communications network in response to receiving the data entry from the pill window technician. Beneficially, allowing the entry at the pill window level rather than waiting for a physician appointment can enhance maintaining remotely located electronic medical records.

4d9. Further, I wish to point out that neither of the cited references teach dispensing of a multi-day supply of unit doses which allows for reclamation of individual sterile doses, versus conventionally dispensing 30 day supplies of medication as non-individually sterile group doses (e.g., non-unit doses). Still further, I wish to point out that neither of the cited references teach procedures for reclaiming unused individual unit packets of, for example, unconsumed sterile items within a 30 day supply of unit packets--which beneficially can enhance stock optimization and cost recovery.

4d10. Accordingly, based upon my review of the cited references and my knowledge of industry practices, I conclude that neither of the cited references teach each and every element of any of the independent claims, Claims 1, 16, 25, 27, 33, 34, and 35, or their respective dependent claims, Claims 2-15, 17-24, 26, 28-32, and 36.

4d11. In summation, based on my knowledge of the medication and professional pharmacy practices and my observations and conclusions presented above, I find that that as neither Chudy, DOH, or Hingoranee, alone, or in combination, teach each claim element of any of the claims, they do not render the claims obvious. Nor do I find there to be a reasonable expectation of success in trying to combine reference teachings, or a motivation by one of ordinary skill in the art to try to do so.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Sec. 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the publication or any patent issued thereon.

FURTHER DECLARANT SAYETH NOT.

Date October 2, 2009

By: Toby Clark, R. Ph., M. Sc., FASHP
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